

K. Valtchev

Vaginal delineation and occluding device

U.S.S.N. 10/715,104

Kindly enter the amendments to the specifications, drawings and claims made herewith in the above mentioned application. The amendments made address the issues raised by you in your communication from April 15, 2008.

#### BRIEF SUMMARY OF THE INVENTION

An object of the present invention is to provide a vaginal delineation and occluding device for use in gynaecological laparoscopic surgical procedures which is an attachment to a uterine mobilizer, such as the Valtchev uterine mobilizer, and is self adjusting to various lengths of cervixes and angles of fornices.

The present invention is a device that inserts and locks into a uterine mobilizer, the device comprises a ring that adjusts in angle. The ring is made to bear against the vaginal fornix, conforming to its angle and providing delineation of that part of the vagina for identification thereof.

In a second embodiment, the ring is also self-adjusting as to the distance from the uterine mobilizer, to accommodate varying lengths of the cervix. This is effected by pivotally mounting the ring onto four telescopic rods or legs, all spring loaded.

~~A third embodiment of the present invention is configured like a cup with a rigid ring, pivotally attached at the top of the cup. Again, the pivotal attachment provides accommodation for varying angles of the fornix.~~

Another object is to provide an occluder to prevent leakage of carbon dioxide from the peritoneal cavity when the vagina is opened laparoscopically. An enlarged portion of an extension at the base of the vaginal delineator, said extension being inserted into the uterine mobilizer, is made to receive a diaphragm made of an elastic material such as plastic, silicon, nylon, etc. The diaphragm obstructs the vaginal cavity toward the outside of the vaginal delineator, preventing leakage of carbon dioxide from the peritoneal cavity.

~~In the third embodiment of the invention, the cup is the occluding apparatus as well as the structure on which the variable angle, rigid ring is mounted.~~

Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

K. Valtchev

Vaginal delineation and occluding device

U.S.S.N. 10/715,104

RECEIVED  
CENTRAL FAX CENTER

MAY 01 2008

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

**Fig.1** is a side elevation view of a uterine mobilizer and vaginal delineating and occluding device;

**Fig.2a** is a first side elevation view of a first embodiment of the vaginal delineating and occluding device;

**Fig2b** is a plan view from the top of the first embodiment of the vaginal delineating and occluding device;

**Fig2c** is a second side elevation view of the first embodiment of the vaginal delineating and occluding device;

**Fig2d** is a plan view from the bottom of the first embodiment of the vaginal delineating and occluding device;

**Fig.2e** is a side elevation view of a telescopic arm for the vaginal delineating and occluding device;

**Fig.3a** is a plan view of a diaphragm for the vaginal delineating and occluding device;

**Fig.3b** is a cross section ~~top view~~ of a diaphragm for the vaginal delineating and occluding device;

**Fig.4a** is a plan view from the top of a second embodiment of the vaginal delineating and occluding device;

**Fig.4b** is a side elevation view of the second embodiment of the vaginal delineating and occluding device;

**Fig.4c** is a plan view from the bottom of the second embodiment of the vaginal delineation and occluding device;

**Fig.4d** is a first side elevation view of a telescopic spring loaded arm for the second embodiment vaginal delineating and occluding device, where the spring is placed between the outer telescopic arm and the distal arm.

**Fig.4e** is a second side elevation view of a telescopic spring loaded arm for the second embodiment vaginal delineating and occluding device, where the spring is placed into the cavity of the outer telescopic arm.

K. Valtchev

Vaginal delineation and occluding device

U.S.S.N. 10/715,104

Fig.5a (**Withdrawn**) is a side elevation view of a third embodiment of the vaginal delineating and occluding device minus a solid ring to clearly show angles;

Fig.5b (**Withdrawn**) is a cutaway side elevation view of a third embodiment of the vaginal delineating and occluding device;

Fig.5c (**Withdrawn**) is a side elevation view of a third embodiment of the vaginal delineating and occluding device, with a pivotally attached solid ring;

Fig.5d (**Withdrawn**) is a plan view from the top of a third embodiment of the vaginal delineating and occluding device;

Fig.6 is a cutaway view of a female pelvis, the vaginal delineating and occluding device being mounted on inserted and locked in a uterine mobilizer and inserted into the vagina;

Fig.7 (New Sheet)( Replacement Sheet) is the third side view of the first embodiment of the vaginal delineation and occluding device showing the tilting of the solid ring;

Fig. 8 (New Sheet)( Replacement Sheet) is the side elevation view of the second embodiment of the vaginal delineation and occluding device showing the change of the distance between the base of the vaginal delineation and occluding device and the solid ring when pressure is applied on the solid ring.

#### DETAILED DESCRIPTION OF THE INVENTION

A first, preferred embodiment of a vaginal delineating and occluding device 100 is shown in Fig.1 along with a uterine mobilizer 110 as disclosed in U.S.Patent 5,562,679 which is hereby incorporated by reference. The vaginal delineating and occluding device 100 is attached to insert and locked in the head 120 of the uterine mobilizer 110 shown in Fig. 6. The device shown in detail in Figs.2a-e is a first embodiment of the vaginal delineating and occluding device 100 of the present invention. A base 205 has an extension 250 for insertion and locking into the head 120 of the uterine mobilizer 110 and is locked therein. The proximal end 215 of the base 205 is for attaching obturators of various lengths. A solid metal ring 200 is pivotally attached to four legs 210, 230, via pins 220 and 270. The distal ends of a first pair of solid legs 210 are firmly affixed to the base 205 via pins 220 about which the ring 200 may pivot. The ring 200 is permitted to pivot about 20° in both directions from a plane perpendicular to a longitudinal axis of the base 205 (Fig.7). This pivoting permits the accommodation of various angles of the vaginal fornix 620 (see Fig.6). The first pair of legs 210 is preferably of a single

K. Valtchev

Vaginal delineation and occluding device

U.S.S.N. 10/715,104

Piece, solid throughout. The second pair of legs **230** is telescopic and comprises a plurality of parts as detailed in Fig.2e. A proximal distal end of a secure distal arm **255** engages a pin **280** to which an inner telescoping arm **265** is pivotally attached. The inner telescoping arm **265** slides into the distal end of an outer telescoping arm **260**. The outer telescoping arm **260** is pivotally attached to the ring **200** at its proximal end by a pin **270**. The outer telescoping arm **260** is a hollow tube to receive the proximal end of the inner telescoping arm **265**. A diaphragm **225** of elastic material such as plastic, nylon, silicon, etc. is shown in Figs.3a and 3b. Its use is to obstruct the vagina for the prevention of and does not allow a flow in any direction carbon dioxide leakage from the peritoneal cavity when the vagina is opened laparoscopically. The diaphragm **225** has a whole **300** in its center through which an enlarged portion **275** of the base **205** of the vaginal delineating and occluding device **100** passes and helps secure the diaphragm 225. When the distal end of the base **205** is inserted in the uterine mobilizer **110**, the diaphragm **225** is held securely between the base **205** and the head of a mobilizer 110, preventing flow in any direction. Various sizes of diaphragms **225** may be supplied to fit a variety of patients. About the circumference of the diaphragm 225 is an enlarged portion 310. A center annulus 320 is thicker than a center membrane 330. The rim 310 and the annulus 320 are thicker than a membrane 330, Fig.3 a-b

A second embodiment of the vaginal delineating and occluding device **100** is shown in Figs.4a-e. In this embodiment all the legs **410** are made as the telescoping legs **410**, described above. In addition, a spring **440** applies a force to separate the solid ring **200** away from the base **205**. The spring **440** may bear directly on the secure distal arm 255 and the outer telescoping arm 260 as shown in Fig.4d; or it may bear on the proximal end of the inner telescoping arm 265 and the solid ring 200 proximal end of the hollow part of the outer telescopic arm as shown in Fig.4e. In this embodiment, the distance ~~location~~ of the solid ring **200** relative to the base **205** is adjustable; when a pressure F is applied to the solid ring which to accommodate various lengths of the cervix. (See Fig. 8)

~~A third embodiment of the present invention is shown in Figs.5a-d. Here, a cup 500 is illustrated the rim of which has a slope in two opposite directions, the slope having an angle, 0, where 0 is about 15°. This cup 500 is inserted and locked attached in the same way into the head 120 of the uterine mobilizer 110 via an extension 250. Pivotaly attached at the top of the cup 500 is a rigid ring 510, preferably constructed of a metallic material. The rigid ring 510 is pivotaly attached at by pins 520 that permit the ring to tilt through the angle, 0, as far as the rim of the cup 500, again, about 15°. The view in Fig.5a is intentionally without the ring 510 to show the angle 0.~~

The ring **510** bears against the fornix **620**, the cup **500** acts to occlude the vagina, replacing the diaphragm **225** of the previous embodiments. The vaginal delineating and occluding device **100**

K. Valtchev

Vaginal delineation and occluding device

U.S.S.N. 10/715,104

~~of the first embodiment is shown in use in Fig. 6. The vaginal delineating and occluding device 100 is inserted into a vagina 610 inserted and locked in the uterine mobilizer 110 until the ring 200 of the vaginal delineating and occluding device 100 rests against the vaginal fornix 620.~~

The above embodiments are the preferred embodiments, but this invention is not limited thereto. It is, therefore, apparent that many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.